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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,283	03/19/2001	Robert L. Fischer	02307O086121	2808

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EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/812,283	FISCHER ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-15 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1.5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings

1. **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The first sentence of the specification indicates that the application is a continuation-in part of U.S. Application 09/071,838 (pending). However, the sentence should indicate that the instant application is a continuation of U.S. Application No. 09/177,249, filed October 22, 1998, now U.S. Patent No. 6,229,064, which is a continuation-in-part of U.S. Application No. 09/071,838, filed May 1, 1998.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example at page 7, line 5. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. Pages 32-42 of the specification present a sequence listing of SEQ ID NOs: 1-6. However, the computer readable form of the sequence listing, as well as a paper copy of the computer readable form received 27 September 2001, consists of 324 sequences. The computer readable form of the sequence listing of the instant application is the same as that of parent application 09/177,249. It is therefore not clear why pages 32-42 of the instant specification present SEQ ID NOs: 1-6. Clarification/correction is required. New matter must be avoided.

Claim Objections

5. Claim 1 is objected to because of the following informalities: the recitation --that is-- appears to be missing in line 2 after "polypeptide." Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2, 4-15 and 17-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-17, and 20-22 of U.S. Patent No. 6,229,064 ('064). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of '064 is directed to isolated double stranded nucleic acid molecules comprising a polynucleotide that hybridizes to SEQ ID NO: 3 under specified conditions and enhance endosperm development in

the absence of fertilization when operably linked to a plant promoter to inhibit gene expression and introduced into a plant. Instant claim 1 is directed to any isolated double-stranded nucleic acid molecule comprising a FIE polynucleotide encoding a polypeptide at least 60% identical to SEQ ID NO: 4. SEQ ID NOs: 3 and 4 of '064 and the instant application are identical, and nucleotide sequence of SEQ ID NO: 3 encodes the amino acid sequence of SEQ ID NO: 4. As the polynucleotides of instant claim 1 encode polypeptides that are at least 60% identical to SEQ ID NO: 4, the claim encompasses the nucleic acid molecules of patented claim 1. Instant claims 2 and 5-14 introduce the same limitations as patented claims 2, 4-6,10, 12-17, 20 and 21. Instant claim 22 limits the nucleic acid molecule to encode a polypeptide that is at least 80% identical to SEQ ID NO: 4, which also encompasses the isolated nucleic acid molecules of patented claim 1. The method of modulating endosperm development in a plant comprising introducing an expression cassette containing a plant promoter operably linked to the polynucleotide of claim 1 of instant claims 15-21 are also obvious over the patented claims, as patented claim 1 indicates that endosperm development is enhanced when the polynucleotide is operably linked to a plant promoter to inhibit gene expression and introduced into a plant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 9-15, 17-21, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2: the recitation "at least about" in line 2 renders the claim indefinite. The range of nucleotides encompassed by the recitation is not clear, making the metes and bounds of the claim unclear.

In claims 9 and 15: there is improper antecedent basis for the recitation "the polynucleotide in claim 1" in line 2 of claim 9 and line 3 of claim 15. Claim 1 is directed to an isolated double-stranded nucleic acid molecule, not a polynucleotide. It is suggested that claims 9 and 15 be amended to indicate that the expression cassette comprises the isolated nucleic acid molecule of claim 5.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2, 5-7, 9, 10, 12, 13, 15, 18, and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated double-stranded nucleic acid molecule comprising any FIE polynucleotide encoding a polypeptide at least 60% identical to SEQ ID NO: 4; or wherein the FIE polynucleotide is at least about 100 nucleotides in length; or wherein the nucleotide molecule further comprises a plant promoter operably linked to the FIE polynucleotide; or wherein the plant promoter is from an FIE3 gene; or wherein the FIE

polynucleotide is in antisense orientation; or a transgenic plant comprising an expression cassette containing a plant promoter operably linked to said polynucleotide; or a method of modulating endosperm development in a plant, the method comprising introducing into the plant an expression cassette containing said polynucleotide operably linked to a plant promoter; or said method wherein the polynucleotide is in antisense orientation.

The specification describes the isolation of the FIE3 (fertilization-independent endosperm) genomic (SEQ ID NO: 5) and cDNA (SEQ ID NO: 3) clones, which encode the amino acid sequence of SEQ ID NO: 4, from Arabidopsis (pages 29-30, Example 2a-b). The specification also indicates that mutant fie Arabidopsis plants were isolated in which the central cell of female gametophytes formed endosperm in the absence of fertilization (page 24, bottom paragraph to page 26, second full paragraph). The specification also indicates that complementation experiments with transgenic plants indicated that the FIE3 allele is dominant over its mutant allele, and that the wild-type allele is then involved in a negative regulatory role, preventing the central cell from initiating endosperm development, and fertilization results in the inactivation of FIE protein, and that the fie mutation results in the production of inactive protein (page 28, first full paragraph).

However, the specification does not describe polynucleotides that encode polypeptides that share about 60% or 80% sequence identity or higher with SEQ ID NO: 4 and which retain its functional activity, other than the claimed nucleic acid molecules of U.S. Patent No. 6,229,064. The specification does not provide any description of the functional domains of SEQ ID NO: 4, and so fails to correlate the structures of the amino acid sequences of SEQ ID NO: 4 that are essential to its function. The specification also discusses methods for isolating FIE nucleic acids

(page 11, third full paragraph to page 12, last paragraph). However, methods of isolation do not describe the structure of the isolated nucleic acids themselves. See University of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA... Accordingly, the specification does not provide a written description of the invention...". Also see Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims encompassing any isolated double stranded nucleic acid molecule comprising a FIE polynucleotide encoding a polypeptide having at least about 60% or 80% identity to SEQ ID NO: 4, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of nucleic acid molecules encompassed by the claims.

9. Claims 1, 2, 5-7, 9, 10, 12, 13, 15, 18, and 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated double stranded nucleic acids of claims 1-11 of U.S. Patent No. 6,229,064 and a method for causing endosperm production in plants in the absence of fertilization, comprising antisense expression of polynucleotides encoding SEQ ID NO: 4 in transgenic plants, does not reasonably provide

enablement for all isolated double-stranded nucleic acid molecules comprising a polynucleotide encoding polypeptides having at least 60% or 80% sequence identity with SEQ ID NO: 4 or modulation of endosperm development in any other manner. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated double-stranded nucleic acid molecule comprising any FIE polynucleotide encoding a polypeptide at least 60% identical to SEQ ID NO: 4; or wherein the FIE polynucleotide is at least about 100 nucleotides in length; or wherein the nucleotide molecule further comprises a plant promoter operably linked to the FIE polynucleotide; or wherein the plant promoter is from an FIE3 gene; or wherein the FIE polynucleotide is in antisense orientation; or a transgenic plant comprising an expression cassette containing a plant promoter operably linked to said polynucleotide; or a method of modulating endosperm development in a plant, the method comprising introducing into the plant an expression cassette containing said polynucleotide operably linked to a plant promoter; or said method wherein the polynucleotide is in antisense orientation.

As discussed above, the specification teaches the isolation of genomic and cDNA clones (SEQ ID NOs: 5 and 3, respectively) encoding the FIE3 polypeptide (SEQ ID NO: 4) from Arabidopsis. Mutant fie Arabidopsis plants were isolated in which the central cell of female gametophytes formed endosperm in the absence of fertilization (page 24, bottom paragraph to page 26, second full paragraph). The specification also indicates that complementation experiments with transgenic plants indicated that the FIE3 allele is dominant over its mutant allele, and that the wild-type allele is then involved in a negative regulatory role, preventing the

central cell from initiating endosperm development, and fertilization results in the inactivation of FIE protein, and that the fie mutation results in the production of inactive protein (page 28, first full paragraph).

However, the specification does not teach polynucleotides that encode polypeptides that share about 60% or 80% sequence identity or higher with SEQ ID NO: 4 and which retain its functional activity, other than the claimed nucleic acid molecules of U.S. Patent No. 6,229,064. The specification does not teach the amino acid sequences that are important to the function of SEQ ID NO: 4, and does not provide any guidance in the amino acid changes that can be made to SEQ ID NO: 4 without affecting its functional activity. In the absence of this guidance undue experimentation would be required by one skilled in the art to make all polynucleotides that encodes polypeptides that share at least about 60% or 80% sequence identity with SEQ ID NO: 4 and test the for retention of functional activity. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

As discussed above, the specification indicates that fie mutant plants, in which the FIE protein is inactive, produced female gametophytes in which the central cell produced endosperm in the absence of fertilization. This indicates that expressing polynucleotides encoding SEQ ID NO: 4 in antisense orientation in transgenic plants, to block expression of FIE3, will cause endosperm development in the absence of fertilization. However, the specification does not

teach that endosperm development was modulated in any other manner. The specification also does not enable modulation of endosperm development in any manner wherein the FIE3 protein is overexpressed in plants. The specification speculates that because FIE is a polycomb gene, which are known to control cell cycling, that enhanced FIE expression can be used to control plant morphology or to increase vegetative growth by preventing the plant from setting seed (page 19, first full paragraph). However, the specification does not teach that transgenic plants overexpressing the claimed nucleic acid molecules actually showed these phenotypes. Kinoshita et al. (Proc. Natl. Acad. Sci., USA, 2001, Vol. 98, pages 14156-14161) introduced a transgene, in which the Arabidopsis FIE gene was fused to a nucleotide sequence encoding green fluorescent protein and operatively linked to the FIE promoter, into Arabidopsis plants. Transgenic plants homozygous for the transgene that were also either homozygous or heterozygous for the wild type FIE allele developed normally (page 14158). The FIE-encoding sequence was also operably linked to the CaMV 35S promoter, and was introduced by genetic crosses into plants that were homozygous for fie. These plants did not display any mutant phenotypes and were indistinguishable from wild-type plants (page 14159). As FIE3 overexpression in transgenic plants does not produce any phenotype distinguishable from wild-type plants, undue experimentation would be required by one skilled in the art to use the claimed method to modulate endosperm development in plants by overexpressing the claimed nucleic acid molecules. It is suggested that claim 15 be amended to indicate that the method causes endosperm development in the absence of fertilization, and that the polynucleotide is in anti-sense orientation. Given the breadth of the claims encompassing isolated double-stranded nucleic acids comprising polynucleotides encoding polypeptides having at least about 60% or

80% identity to SEQ ID NO: 4, or a method to modulate endosperm development in any manner, comprising overexpressing the claimed nucleic acid molecules in sense orientation, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

10. No claim is allowed.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

July 12, 2002

ASHWIN D. MEHTA, PH.D
PATENT EXAMINER